

In the claims:

For the convenience of the Examiner, all claims being examined, whether or not amended, are presented below.

Please cancel, without prejudice, previously withdrawn claims 5 and 25

1. **(Previously presented)** A pharmaceutical composition that provides an elastin-based composition for localized delivery in vivo, said elastin-based composition comprising a polypeptide, wherein said polypeptide comprises (i) an amino acid sequence at least 95% identical to SEQ ID NO: 3, (ii) a bioactive fragment of SEQ ID NO: 3 that includes six or seven repeats of a hexameric sequence represented by SEQ ID NO: 1, or (iii) a peptide fragment consisting essentially of six or seven repeats of the hexameric sequence represented by SEQ ID NO: 1, wherein said elastin-based composition is attached to a biocompatible support or dissolved in a biocompatible matrix and has one or more biological activities selected from the group consisting of:

- a) inhibiting the proliferation of smooth muscle cells in vivo;
- b) stimulating the differentiation of smooth muscle cells in vivo;
- c) regulating the migration of smooth muscle cells in vivo; and
- d) binding to smooth muscle cells, and

wherein said elastin-based composition has an IC50/EC50 for at least one of said biological activities that is less than or equal to  $10^{-3}$ .

2. **(Original)** The pharmaceutical composition of claim 1 wherein said elastin-based composition is soluble and has an IC50/EC50 for each of said one or more biological activities that is less than or approximately equal to  $10^{-3}$ .

3. **(Previously presented)** The composition of claim 1 or 2 wherein said IC50/EC50 is greater than  $10^{-15}$ .

4. **(Original)** The composition of claim 1 wherein said pharmaceutical composition provides a dose of said elastin-based composition equivalent to  $10^{-8}$  M of a peptide having the amino acid sequence of SEQ ID NO:2 at said target site.
5. **(Cancelled)**
6. **(Previously presented)** The composition of claim 1 wherein said elastin-based composition comprises a recombinant polypeptide.
7. **(Previously presented)** The composition of claim 1 wherein said elastin-based composition comprises a synthetic peptide.
8. **(Previously presented)** The composition of claim 7 wherein said synthetic peptide comprises six repeats of the hexameric sequence Val-Gly-Val-Ala-Pro-Gly (SEQ ID NO: 1).
9. **(Previously presented)** The composition of claim 7 wherein said synthetic peptide comprises seven repeats of the hexameric sequence Val-Gly-Val-Ala-Pro-Gly (SEQ ID NO: 1).
10. **(Original)** The composition of claim 1, wherein said elastin-based composition is crosslinked, precipitated, or coacervated.
11. **(Original)** The composition of claim 1 wherein said elastin-based composition comprises an elastin matrix produced from a blood vessel.
12. **(Previously presented)** The composition of claim 1 wherein said elastin-based composition is attached to a biocompatible support or biocompatible matrix.
13. **(Previously presented)** The composition of claim 12 wherein said biocompatible support or biocompatible matrix comprises a tube.

14. **(Previously presented)** The composition of claim 13 wherein said elastin-based composition is attached to an outer surface of said tube and additionally comprises a sheath encircling said tube.

15-21. **(Cancelled)**

22. **(Currently amended)** A method for prophylaxis or treatment of a disorder having diminished capacity to regulate smooth muscle cell function comprising delivery of the elastin-based composition provided by the pharmaceutical composition of any of claims 1, 60 or 67 to a site of diminished capacity to regulate smooth muscle cell function, wherein said disorder is restenosis, and wherein said elastin-based composition is delivered via a biocompatible support.

23. **(Previously presented)** The method of claim 22 wherein said IC<sub>50</sub>/EC<sub>50</sub> is greater than about 10<sup>-15</sup>.

24. **(Original)** The method of claim 22 wherein said pharmaceutical composition provides a dose of said elastin-based composition equivalent to 10<sup>-8</sup> M of a peptide having the amino acid sequence of SEQ ID NO:2 at said target site.

25. **(Cancelled)**

26. **(Previously presented)** The method of claim 22 wherein said elastin-based composition comprises a recombinant polypeptide.

27. **(Previously presented)** The method of claim 22 wherein said elastin-based composition comprises a synthetic peptide comprising 6 repeats of the hexameric sequence Val-Gly-Val-Ala-Pro-Gly (SEQ ID NO: 1).

28. **(Original)** The method of claim 22 wherein said elastin-based composition is crosslinked, precipitated, or coacervated.

29. **(Original)** The method of claim 22 wherein said elastin-based composition comprises an elastin matrix produced from a blood vessel.

30. **(Currently amended)** The method of claim 22, wherein said ~~elastin-based composition is attached to a biocompatible support~~ is a stent ~~or a biocompatible matrix~~.

31. **(Previously presented)** The method of claim 30 wherein said biocompatible support or biocompatible matrix comprises a tube.

32. **(Previously presented)** The method of claim 22 wherein said target site is located in the cardiovascular system and is suspected or known to be at risk for restenosis.

33. **(Original)** The method of claim 22 wherein delivery comprises intravascular delivery of said elastin-based composition directly to a vascular site.

34. **(Cancelled)**

35. **(Original)** The method of claim 22 wherein said elastin-based composition is delivered to and maintained at said site.

36-47. **(Cancelled)**

48. **(Previously presented)** The pharmaceutical composition of claim 1, wherein said elastin-based composition comprises a polypeptide comprising (i) an amino acid sequence identical to SEQ ID NO: 3, (ii) a bioactive fragment of SEQ ID NO: 3 that includes six or seven repeats of a hexameric sequence represented by SEQ ID NO: 1, or (iii) a peptide fragment consisting essentially of six or seven repeats of the hexameric sequence represented by SEQ ID NO: 1, wherein said elastin-based composition is attached to a biocompatible support or dissolved in a biocompatible matrix and has one or more biological activities selected from the group consisting of:

a) inhibiting the proliferation of smooth muscle cells in vivo;

- b) stimulating the differentiation of smooth muscle cells in vivo;
- c) regulating the migration of smooth muscle cells in vivo; and
- d) binding to smooth muscle cells, and

wherein said elastin-based composition has an IC<sub>50</sub>/EC<sub>50</sub> for at least one of said biological activities that is less than or equal to 10<sup>-3</sup>.

49. **(Previously presented)** The pharmaceutical composition of claim 48, wherein said peptide fragment consists essentially of six repeats of the hexameric sequence represented by SEQ ID NO: 1.

50. **(Previously presented)** The pharmaceutical composition of claim 1, wherein said elastin-based composition is derivatized by linkage to one or more additional chemical groups for promoting sustained release.

51-55. **(Cancelled)**

56. **(Previously presented)** The composition of any of claims 1, 8, 9, 60 or 67, where said elastin-based composition is dissolved or suspended within a biocompatible polymer matrix, which matrix permits diffusion of the elastin-based composition, to form a sustained-release composition.

57. **(Previously presented)** The composition of claim 56, wherein the biocompatible polymer matrix is selected from the group consisting of polyester, a polylactide, degradable lactic acid-glycolic acid copolymers, and poly-D-(-) hydroxybutyric acid.

58. **(Previously presented)** The composition of claim 56, wherein the biocompatible polymer matrix is formulated for coating an implantable medical device.

59. **(Previously presented)** The composition of claim 56, wherein the biocompatible polymer matrix is formulated for coating a stent.

60. **(Previously presented)** A pharmaceutical composition that provides an elastin-based composition, said elastin-based composition comprising a polypeptide, wherein said polypeptide consists essentially of (i) an amino acid sequence at least 95% identical to SEQ ID NO: 3, (ii) a bioactive fragment of SEQ ID NO: 3 including six or seven repeats of the hexameric sequence represented in SEQ ID NO: 1, or (iii) a peptide fragment consisting essentially of six or seven repeats of the hexameric sequence represented by SEQ ID NO: 1, wherein said elastin-based composition is attached to a biocompatible support or dissolved in a biocompatible matrix and has one or more biological activities selected from the group consisting of:

- a) inhibiting the proliferation of smooth muscle cells;
- b) stimulating the differentiation of smooth muscle cells;
- c) regulating the migration of smooth muscle cells; and
- d) binding to smooth muscle cells, and

wherein said elastin-based composition has an IC<sub>50</sub>/EC<sub>50</sub> for at least one of said biological activities that is less than or equal to 10<sup>-3</sup>.

61. **(Previously presented)** The composition of claim 60, wherein said polypeptide consists essentially of (i) an amino acid sequence identical to SEQ ID NO: 3, (ii) a bioactive fragment of SEQ ID NO: 3 that includes six or seven repeats of the hexameric sequence represented in SEQ ID NO: 1 or (iii) a peptide fragment consisting essentially of six or seven repeats of the hexameric sequence represented by SEQ ID NO: 1.

62. **(Previously presented)** The composition of claim 60, wherein said polypeptide consists essentially of (i) an amino acid sequence identical to SEQ ID NO: 3, (ii) a bioactive fragment of SEQ ID NO: 3 that includes seven repeats of the hexameric sequence represented in SEQ ID NO: 1, or (iii) a peptide fragment consisting essentially of seven repeats of the hexameric sequence represented by SEQ ID NO: 1.

63. **(Previously presented)** The composition of claim 60, wherein said bioactive fragment or peptide fragment includes six repeats of the hexameric sequence represented in SEQ ID NO: 1.

64. **(Cancelled)**

65. **(Previously presented)** The composition of claim 60, wherein said bioactive fragment or peptide fragment consists essentially of six repeats of the hexameric sequence represented in SEQ ID NO: 1.

66. **(Cancelled)**

67. **(Previously presented)** A pharmaceutical composition that provides an elastin-based composition, said elastin-based composition consisting essentially of a polypeptide, wherein said polypeptide consists essentially of (i) an amino acid sequence at least 95% identical to SEQ ID NO: 3, (ii) a bioactive fragment of SEQ ID NO: 3 that includes six or seven repeats of the hexameric sequence represented in SEQ ID NO: 1, or (iii) a peptide fragment consisting essentially of six or seven repeats of the hexameric sequence represented by SEQ ID NO: 1, wherein said elastin-based composition is attached to a biocompatible support or dissolved in a biocompatible matrix and has one or more biological activities selected from the group consisting of:

- a) inhibiting the proliferation of smooth muscle cells;
- b) stimulating the differentiation of smooth muscle cells;
- c) regulating the migration of smooth muscle cells; and
- d) binding to smooth muscle cells, and

wherein said elastin-based composition has an IC<sub>50</sub>/EC<sub>50</sub> for at least one of said biological activities that is less than or equal to 10<sup>-3</sup>.

68. **(Previously presented)** The composition of claim 67, wherein said polypeptide consists essentially of (i) an amino acid sequence identical to SEQ ID NO: 3, (ii) a bioactive fragment of SEQ ID NO: 3 that includes seven repeats of the hexameric sequence represented in SEQ ID NO: 1, or (iii) a peptide fragment consisting essentially of seven repeats of the hexameric sequence represented by SEQ ID NO: 1.

69. **(Previously presented)** The composition of claim 67, wherein said polypeptide consists essentially of (i) an amino acid sequence identical to SEQ ID NO: 3, (ii) a bioactive fragment of

SEQ ID NO: 3 that includes six repeats of the hexameric sequence represented in SEQ ID NO: 1,  
or (iii) a peptide fragment consisting essentially of six repeats of the hexameric sequence  
represented by SEQ ID NO: 1.

70-73. **(Cancelled)**